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09/876,311	06/07/2001	Maurice Ronan Goodman	7802-A08-002	8420
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PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER GOTTSCALK, MARTIN A	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/876,311

Applicant(s)

GOODMAN ET AL.

Examiner

MARTIN A. GOTTSCHALK

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. Claims 1-6, 8, 9, and 12-23 are pending. Claims 1-6, 14-16, 22, and 23 have been examined. Independent claim 1 is amended. Claims 4 and 14-16 are previously presented. Claims 2, 3, 5, and 6 are as per the original. Claims 22 and 23 are new. Claims 8, 9, 12, 13 and 17-21 are withdrawn. Claims 7, 10 and 11 are cancelled.

Election/Restrictions

2. Newly submitted claims 22 and 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They recite at least the following features not present in the elected inventions:

combining the plurality of general programme areas and the plurality of specific programme areas into a programme of the disease management programme;

offering the programme comprising the plurality of general programme areas and the plurality of specific programme areas that have been combined to a plurality of members of the disease management programme, wherein at least two members in the plurality of members each comprise a different disease;

determining that at least one member in the plurality of members has participated in at least one programme area in at least one of the plurality of general programme areas and the plurality of specific programme areas.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22 and 23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown as applied to claims 1 and 8 above, in view of Bro (US Pat# 5,722,418, hereinafter Bro).

As per claim 1, Brown discloses a method of incentivising members of a disease management programme to comply with the programme (Brown: col 5, Ins 14-16), the method comprising the steps of:

(a) defining a plurality of specific programme areas (Brown: col 12, Ins 23-25.

See also the Bro reference below which teaches other aspects of this step);

(c) awarding points to a member of each of the specific programme areas in which the member participates, only if the member is afflicted with a disease, to which the specific programme area in which the member participates has been determined to be of particular benefit (Brown: col 8, Ins 37-53; col 23, Ins 45-57);

(d) calculating the total number of points awarded to the member (Brown: col 11, Ins 33-36, reads on "fulfilled the evaluation criteria"; col 23, Ins 45-57. See the Bro reference below for the "allocating" step).

Brown teaches general program areas of disease, such as diabetes and asthma (Brown: col 12, lns 18-23), with specific programs areas for individual patients having the same general disease (e.g. Brown: Fig 24, note the two diabetes plans), but does not explicitly provide the feature in claim 1 of

defining a plurality of general programme areas,

where the general programme areas are not related to specific programme areas. However, this teaching is provided by Bro who teaches general programme areas such as exercise (Bro: col 11, ln 20) as well as specific programme areas, see below.

In addition, Brown fails to explicitly teach awarding points separately to general and specific program areas, and associated levels of performance as recited in claim 1, however these features are well known as taught by Bro, who discloses

(a) wherein the plurality of general programme areas are programme areas that if complied with will be of benefit to a member stricken with any disease managed by the disease management programme (e.g. Bro: col 11, ln 20, "exercise")

and

wherein the plurality of specific programme areas are programme areas that are determined to be of particular benefit to a member afflicted with some but not all of the diseases managed by the disease management programme (e.g. Bro: col 12, Ins 47-53, i.e. "chronic diseases");

and

(b) awarding points (e.g. Bro: col 40, Ins 31-33, reads on "credits"; col 41, Ins 34-38, i.e. "reinforcer"; col 38, Ins 50-64) to a member for each of the general programme areas in which the member participates, the points being allocated to members based on a multi-level system (Bro: col 60, Ins 52-62, multi-level reads on "graded"), including:

a first level, wherein the member is awarded points for merely taking part in a programme area (Bro: col 40, Ins 34-49, see below for the "second level" feature),

and

a third level, wherein the member is awarded points for attaining a minimum level for a measurable of a programme area associated with a disease with which the member is afflicted (Bro: col 40, Ins 34-49).

However, Bro teaches a method and system of behavioral modification which uses rewards to reinforce desired behavior (e.g. Bro: col 41, Ins 34-38). The teachings include applying the method to both 1) general (e.g. Bro: col 11, In 20, "exercise") program areas, where participation would be valuable to a patient regardless of the patient's disease state, and 2) specific areas, such as programs relating to specific chronic diseases (e.g. Bro: col 12, Ins 47-53).

In addition, Brown teaches providing a reward to a patient for attaining a predetermined compliance goal (Brown: col 23, Ins 45-57), but fails to explicitly teach the feature of claim 1 which recites

(e) allocating a reward to the member if the total number of points awarded to the member accumulate to a predetermined amount.

However this feature is well known as taught by Bro: col 40, Ins 31-40. Bro teaches the use of credits which are awarded for successfully achieving a performance goal. The credits may be accumulated and applied to a future reward (reads on "premiums or other inducements").

For all of the above combinations of Bro with Brown, it would have been obvious to incorporate the teachings of Bro allowing for reward programs applicable to general and specific areas, with the health care compliance system of Brown with the motivation of leveraging the ability of an expert to affect behavioral change using telecommunications systems (Bro: col 5, Ins 48-52).

Bro explicitly teaches use of rewards (Bro: col 40, Ins 31-33) to improve compliance with one or more health-related programs (e.g. Bro: col 53, Ins 4-6). Bro further teaches that performance credits may be accumulated for to apply to an award in the future (Bro: col 40, Ins 31-40). Bro further teaches that the reward protocols may be provided in degrees, or levels (Bro: col 60, Ins 52-62, i.e. graded) and that rewards for gradually increased performance (Bro: col 52, Ins 14-19) and motivation (Bro: col 59, Ins 57-62) are effective. Bro does not explicitly recite the "bonus points" aspect of feature of claim 1 as in

a second level, wherein the member is awarded a bonus set of points in addition to the points awarded in the first level in response to participating in all programme areas associated with a disease with which the member is afflicted.

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However, it would have been obvious to one of ordinary skill in the art to infer that a graded reward protocol would include an increased reward of credits (i.e. a bonus set of points) for improved performance in a medical regimen in order to fulfill the promise of the graded reward protocol (e.g. one would get more for an "A" than a "B" level performance).

As per claim 2, Brown discloses a method according to claim 1, wherein

points are only awarded to the member if the member participates in all of the programme areas which are associated with the disease or diseases with which the member is afflicted (Brown: Fig. 15A and 15B; col 13, ln 19 to col 14, ln 37; Figs. 10 and 11. Note that both criteria of questions being answered and measurements being within limits must be met if the coupon is to be given.)

As per claim 3, Brown discloses a method according to claim 1 wherein

additional points are awarded to the member if the member participates in all of the programme areas which are associated with the disease or diseases with which the member is afflicted (The Examiner notes the rejection provided for claim 2 above and further notes that a repetition of this process would result in additional coupons being given. Repetition of the process would be expected for patients involved in disease management programs associated with chronic

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diseases such as the examples of diabetes and asthma cited in the Brown reference).

As per claim 4, Brown discloses a method according to claim 1 wherein

the general programme areas is

education (Brown col 16, Ins 26-35).

but fails to disclose the remaining features of the claim which is well known in the art as evidenced by the teachings of Bro who teaches

the general programme areas are some of

diet,

exercise,

and

smoking (Bro: col 11, Ins 12-24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Bro within the method of Brown with the motivation of implementing and reinforcing a patient's medical regimens (Bro col 40, lns 25-27).

As per claim 5, Brown discloses a method according to claim 1 wherein

the specific programme areas are one or more of

blood pressure,

flow volume loop measurement,

influenza vaccine,

pneumococcal vaccine,

cholesterol

and

long term glucose control (Brown: Fig. 5A; Fig 5B, item 124; Fig. 6A).

As per claim 6, Brown discloses a method according claim 1 further including the steps of:

(a) defining a measurable within at least one of

the general (Brown: col 23, lns 45-57; Figs. 15A and 15B, the Examiner notes that the overall evaluation criteria involves both the compliance questions of Fig 15A, item 412, and the physiological measurements of Fig. 15B, items 420-424)

or

specific programme areas (Brown: col 5, ln 66 to col 6, ln 15, i.e. data from one of the monitoring devices)

so that a members performance within said programme area can be ascertained;

(b) defining a minimum level of the measurable, which minimum level indicates a minimum required level of member performance within the at least one programme area (Brown: col 8, 48-53); and

(c) awarding points to a member if the member obtains the defined minimum level of a measurable for the at least one programme area only if the member is afflicted with a disease which is associated with that particular programme area (Brown: col 8, Ins 37-53).

As per claims 14 and 15, Brown fails to explicitly disclose the features of these claims, however, they are well known in the art as evidenced by the teachings of Bro who teaches

a method according to claim 1 wherein

(claims 14) the amount of the reward is related to the amount of points accumulated by the member.

and

(claims 15) the reward is a cash payout or special options on services
(for both claims, see Bro: col 38, In 5, to col 39, In 10; col 34, Ins 3-18 and 31-56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Bro within the method of Brown with the

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motivation of implementing and reinforcing a patient's medical regimens (Bro col 40, Ins 25-27).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Bro as applied to claims 15, and further in view of Sehr (US Pat# 6,085,976, hereinafter Sehr).

As per claim 16, Brown and Bro fail to teach the features of the claim, however, these features are well known in the art as evidenced by the teachings of Sehr who teaches a method according to claim 15

wherein the services are one or more of

airplane tickets,

hotel accommodations,

and

car rentals (Sehr: col 32, ln 64 to col 33, ln 48, note the use of "frequent mileage points" as rewards).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Sehr with the combined teachings of Brown and Bro with the motivation of reducing the administrative costs associated with non-computerized systems (Sehr: col 2, lns 7-26).

Response to Arguments

7. Beginning on page 13 of the response, Applicant first appears to argue that Brown does not teach the feature of general programme areas. In response, clarification has been provided in the new grounds of rejection for this feature in the rejection of claim 1 above which shows that the Bro reference contains both general and specific programme areas, as discussed in the Office Action of 11/30/2007.

On the same page, Applicant argues that the Brown reference "...never determines if a member is afflicted with a disease that is associated with the specific program area..." In response, the Examiner notes that the reference is replete with the teachings of patients participating in treatment for diseases such as diabetes (see for example Figs 5 and 24) for which a reward is provided if they comply with the regimen, as cited above.

On page 14 Applicant argues that Brown does not teach the "allocating" step of claim 1. In response, new grounds of rejection are provided above in the rejection of this feature of claim 1 using the Bro reference.

On page 16 of the response, Applicant asserts that, "Bro fails to teach or suggest the nexus between general program areas and specific programme areas recited by the

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presently claimed invention." In response, the Examiner does not see that a nexus is recited in the claims. Citations for the distinct features pertaining to the two types of programme areas are provided (e.g. "exercise" as the general area which would benefit any disease, then the specific areas associated with "chronic diseases."), and Applicant's assertions are not persuasive seen that any further evidence is required to reject these features.

On the same page, Applicant argues that the "second level" feature of claim 1 is not taught by Bro. In response, new grounds of rejection have been provided above.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN A. GOTTSCHALK whose telephone number is (571)272-7030. The examiner can normally be reached on Mon - Fri 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James A. Kramer can be reached on (571) 272-6783. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. A. G./
Examiner, Art Unit 3693

/Jason M Borlinghaus/
Primary Examiner, Art Unit 3693
July 7, 2010